



Research Article

RASAYANA AND IMMUNOMODULATORY EFFECT OF MADHURAUSHADHA SIDDHA AVALEHA IN 6TH AND 7TH MONTH OF PREGNANCY – A RANDOMIZED COMPARATIVE CLINICAL TRIAL

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KEYWORDS: *Garbhini Paricharya, Vyadhikshamatwa, Rasayana, Immuno-modulator.*

ABSTRACT

Background: *Garbhini Paricharya* (Antenatal care) has got its own importance in the traditions, cultures and in medical fraternity from time immemorial. A special diet, unique life style and significant importance have been given to the pregnant women. Supplementation of *Madhuraushadha* having *Rasayana* properties, emphasized in the *Garbhini Upachara*, imparts *Deerghayu, Medha, Arogya, Smriti, Prabha, Varna, Deha Bala, Indriya Bala* etc. Incorporating such a therapy in *Garbhini Paricharya* not only benefits the pregnant lady but also for the growing baby in her womb. **Objective:** To evaluate the efficacy of *Madhuraushadha Siddha Avaleha* as *Garbhini Rasayana* in 6th and 7th month of pregnancy and its influence on maternal immune system.

Material and method: It is a randomized comparative clinical trial wherein 30 pregnant ladies fulfilling the selection criteria were randomly divided to 2 groups. The trial group (n=15) was given *Madhuraushadha Siddha Avaleha* 12gm, twice a day. In the control group (n=15) calcium (Shelcal 500mg) and iron (Heam-up Gems 200mg) supplements were administered once a day during 6th and 7th month of pregnancy. **Result:** Patients treated with *Madhuraushadha Siddha Avaleha* showed significant results in maternal weight gain (P<0.001), increase in the maternal immunity level IgG (P=0.030), IgM (P=0.011), increase in serum calcium levels (P=0.005) and also in overcoming the physiological hindrances of pregnancy mainly loss of appetite (P<0.001), heart burn (P<0.001), constipation (P=0.019) etc.

Conclusion: The present study confirms the nutritional benefits, *Rasayana* action and immuno-modulatory effect of *Madhuraushadha Siddha Avaleha* fulfilling the overall nutritional needs during the 6th and 7th month of pregnancy.

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INTRODUCTION

Women's body goes through a great deal of hormonal, physiological, and physical changes during pregnancy. The way, body is nourished during this process will affect maternal as well as the fetal health. According to Ayurveda, for the proper development and growth, the fetus derives nutrition solely from the *Ahara Rasa*^[1] of the mother, which simultaneously may induce *Rasadhatu Kshaya* in the pregnant woman

causing various discomforts due to nutritional deprivation from the very initial stages of pregnancy. Particularly in the 6th and 7th month, where the growth and development is very rapid, extra care has to be taken regarding diet and nutrition of the mother as it directly influences the fetal growth. Though the supplementation of iron, calcium and vitamins are the basic requirement of pregnancy health care, if we can

think of nourishing the mother with something more which not only maintains the pregnancy and takes care of deficiencies, but also does all round development of fetus including improvement of immunological status and prevention of diseases which may manifest in later life, then it would be a thrilling and most cherishing dream of the would-be parents.

Ayurveda emphasizes the importance of *Madhura* drugs endowed with *Rasayana* (rejuvenating and immunomodulatory) properties in *Garbhini Paricharya*.^[2] Considering the significance of immunomodulatory^[3] effect and tissue nourishment by the *Rasayana*,^[4] this concept is utilized in the current study. *Rasayana* therapy in pregnancy introduces a new concept of nutrition creating a healthy intrauterine environment. It acts through the mechanism of specific molecular nutrition to the target organs and also increases bioavailability of better quality nutrients,^[5] causing nourishment to *Rasa Dhatu* to *Shukra Dhatu* even up to *Ojas*^[6] in both the mother and the fetus.

Though *Rasayana* therapy is widely used in Ayurveda practice, till date no clinical data has been reported regarding the effect of *Rasayana* in pregnancy fulfilling the nutritional demands,

overcoming physiological hindrances and boosting the immunity during pregnancy. Therefore the present study was planned to assess the role of *Madhuraushadha Siddha Avaleha* as *Rasayana* in *Garbhini* during 6th and 7th month of pregnancy.

MATERIALS AND METHODS

Source of data

Pregnant women completing their 5th of pregnancy were selected for the study. A special proforma was prepared with details of history taking, physical signs and symptoms, laboratory investigations as mentioned in classics and allied sciences. Parameters of signs and symptoms and investigations were scored on basis of standard method and analyzed statistically. The trial was registered in CTRI [Reg. No. CTRI/2016/10/007373] and institutional ethical clearance was also obtained [SDMCAU/ACA-49/EC12/11-12].

Preparation of drugs

Those *Madhura* drugs which are seen common in *Madhura Gana* mentioned in *Brihat Trayi*^[7,8,9] and having immuno-modulatory, *Rasayana* properties were selected and made into *Avaleha* form with further addition of *Ghrita*, *Khanda Sharkara* and *Prkashepaka Dravya*. (Table 1).

Table 1: Ingredients of Madhuraushadha Siddha Avaleha

S No	Ingredient	Botanical name	Family
1.	<i>Draksha</i>	<i>Vitis vinifera</i> (L.)	Vitaceae
2.	<i>Kharjura</i>	<i>Phoenix sylvestris</i> (L.) Roxb	Palmae
3.	<i>Gokshura</i>	<i>Tribulus terrestris</i> (L.)	Zygophyllaceae
4.	<i>Bala</i>	<i>Sida cordifolia</i> (L.)	Malvaceae
5.	<i>Jivanti</i>	<i>Leptadina reticulata</i> W.& A	Asclepiadaceae
6.	<i>Vamshalochana</i>	<i>Bambusa arundinaceae</i> (Willd.)	Graminae
7.	<i>Mudgaparni</i>	<i>Phaseolus trilobus</i> (AIT.)	Fabaceae
8.	<i>Shatavari</i>	<i>Asparagus racemosa</i> (Willd.)	Liliaceae
9.	<i>Mashaparni</i>	<i>Teramnus labialis</i> (L.f.) Spreng.	Fabaceae
10.	<i>Ashwagandha</i>	<i>Withania somnifera</i> (L.) Dunal	Solanaceae

Grouping and posology

The registered 30 pregnant women were randomly placed in two groups consisting of 15 subjects each. Details of the groups and treatment protocol are mentioned in Table 2. Dietary instructions were given to both the groups.

Table 2: Treatment protocol

Group	Drug	Dosage	Route	Anupana	Duration
Trial (n=15)	<i>Madhuraushadha Siddha Avaleha</i>	12gm BD	orally	Milk	2 months
Control (n=15)	Calcium carbonate (Shelcal) Ferrous sulphate (Heamup Gems)	500mg OD 200mg OD	orally	Water	2 months

Study design

A randomized comparative clinical study with pre-test and post-test design.

Inclusion criteria

- Both primi and multi gravida were included.
- Subjects in between 20-24 weeks of pregnancy.
- Subjects were limited to the age group of 20 – 35 years.
- Subjects having Hb% between >8 Grams.

Exclusion criteria

- Pregnancy complicated with intra-uterine growth retardation, bleeding per vagina, abruptio placenta, placenta previa, pre-eclampsia, oligo/polyhydraminos, multiple pregnancy, gestational diabetes, sickle cell anemia, thalassemia, co-existing fibroids.
- Systemic diseases like hypertension, diabetes mellitus, human immuno-deficiency virus infection, cardio vascular disorders, thyroid dysfunction, hepatitis B etc.

Assessment criteria

On the basis of signs and symptoms, scoring pattern was developed and subjective parameters were assessed. Objective parameters were mainly based on investigations carried out before and after the study.

Subjective parameters

Appetite, Back ache, Cramps in the leg, Constipation, Flatulence, General weakness, Heart Burn, Heaviness of the body, Pallor, Pedal edema, pulling type of pain in legs, Seasonal/recurrent infections like cough/cold etc in the mother

Objective parameters

Maternal weight gain, hematological tests, immunoglobulin study.

Investigations

Routine antenatal investigations, WBC, Serum calcium, Serum iron, Serum ferritin, Study of maternal immunoglobulin G (IgG) and immunoglobulin M (IgM) before and after the study.

Statistical analysis

Paired 't' test was adapted to assess the changes in the values before and after treatment within the group. Un paired 't' test to compare between two groups.

RESULTS AND DISCUSSION

Effect of the drug on physiological hindrances during pregnancy

Loss of Appetite and Heart burn showed statistical significant results in trial group (Table 3). Other

subjective parameters such as pedal edema, cramps in the leg, constipation, backache, pulling pain in legs, heaviness of the body, recurrent common infections also showed marked improvement in the trial group.

Loss of Appetite: Diminished GIT activity during pregnancy lead to disturbance in the *Agni* causing *Aruchi*, *Agnimandhya* symptoms. *Dipana*, *Pachana* and *Rochana* properties of the trial drug were efficient in overcoming the loss of appetite.

Pedal edema: Though not present initially in both the groups as pedal edema usually develops in last trimester of pregnancy, *Shotahara* and *Mutrala* properties of *Gokshura*, *Bala*, *Mashaparni* etc could have decreased the incidence of development of *Pada Shopha* even during 7th month where as in the control group pedal edema had significantly increased.

Cramps in the legs: Reduced significantly in the trial group. *Madhuraushadha Siddha Avaleha* consisting of *Kshira*, *Ghritha*, *Kharjura* etc., efficiently fulfilled the calcium needs relieving the cramps in the leg. In the control group however direct calcium was supplemented, the change was insignificant.

Heart burn: *Vidaha* is mostly due to the *Pitta* vitiation. The *Shita Virya*, *Pitta Shamaka* and *Dahanigraha* properties alleviated the heart burn, whereas, iron and calcium tablets in control group increased the heart burn in patients.

Backache and pulling type of pain in legs: *Vatahara* property chiefly seen in the *Madhura* drugs present in *Avaleha*, mitigates the *Vata* which is the main cause of *Shoola*. *Balya* property strengthens the bones and muscles alleviating the backache. While in control group backache increased significantly and the pulling pain in legs showed no reduction but remained constant.

Flatulence: *Vataanulomana* property by virtue of which, flatulence was subsided efficiently in the trial group. While in control group flatulence increased considerably.

Constipation: Constipation in pregnancy is mainly due to atonicity of the gut and the diminished peristalsis. Vitiation of *Vata* in *Koshta*, *Pakvashaya* and *Guda* also results in constipation. *Vataanulomana* and *Vatashamaka* properties may improved the peristalsis. *Kshira* being laxative might also have contributed in relieving constipation. None of the drugs in trial group caused constipation as a side effect unlike in the control group.

Heaviness of the body: *Gurugatrata* being a symptom of *Ama*, was decreased considerably in

the trial group. This may be due to the *Dipana*, *Pachana* and *Vataanulomana* action of the trial drug which might have done *Amapachana* and improved the *Agni*, thereby reducing the heaviness of the body. Heaviness was increased in the control group.

Pallor: It is an alarming sign of iron deficiency anemia. As the drug did not fulfill the expected iron needs in pregnancy, pallor was increased in the trial group which corresponded to the reduction in the hemoglobin concentration.

Recurrent infections: The trial drug having *Jivaniya*, *Rasayana*, *Balya* and *Brumhana Guna* could have possibly increased the *Poshaka Rasa* there by further nourishment of the consecutive *Dhatus* and finally improvement in the *Ojas* and *Bala* resulting in increase in *Vyadhikshamatwa*. The increase in immunoglobulins by the immunomodulatory effect of the drugs also suggests the improved immunity status in the trial group, while in control group there was slight increase in the episodes of frequent minor infections.

Table 3: Effect of the drug on physiological hindrances during pregnancy

Parameters		Within the group (paired 't' test)					Between the group (unpaired 't' test)			
		Mean BT	Mean AT	D	t	P	d	T	P	df
Loss of Appetite	MS	0.800	0.0667	0.733	4.036	0.001	0.733	4.602	<0.001	28
	IC	0.933	0.800	0.133	0.807	0.433				
Pedal edema	MS	0.000	0.200	0.200	1.871	0.082	0.400	2.049	0.050	28
	IC	0.000	0.600	0.600	3.674	0.003				
Cramps in leg	MS	0.800	0.400	0.400	3.055	0.009	0.000	0.000	1.000	28
	IC	0.600	0.400	0.200	1.382	0.189				
Heart burn	MS	0.667	0.133	0.533	3.228	0.006	1.000	4.279	<0.001	28
	IC	0.600	1.133	0.533	2.779	0.015				
Backache	MS	0.667	0.400	0.267	1.169	0.262	0.467	2.214	0.035	28
	IC	0.333	0.867	0.533	3.228	0.006				
Pulling Pain in Legs	MS	0.733	0.533	0.200	1.146	0.271	0.0667	0.287	0.776	28
	IC	0.600	0.600	0.000	0.000	1.000				
Flatulence	MS	0.733	0.133	0.600	3.674	0.003	0.400	2.479	0.019	28
	IC	0.333	0.533	0.200	1.382	0.189				
Constipation	MS	0.400	0.066	0.333	2.646	0.019	0.467	2.619	0.014	28
	IC	0.400	0.533	0.133	0.807	0.433				
Heaviness	MS	0.400	0.200	0.200	1.871	0.082	0.600	3.334	0.002	28
	IC	0.600	0.800	0.200	1.000	0.334				
Pallor	MS	0.467	0.733	0.267	2.256	0.041	0.400	1.809	0.081	28
	IC	0.733	0.333	0.400	2.449	0.028				
Minor infections (cold, cough, allergy etc)	MS	0.933	0.267	0.667	2.870	0.012	0.200	0.887	0.382	28
	IC	0.400	0.467	0.066	0.564	0.582				

MS- Madhuraushada Siddha Avaleha Group IC-Iron and calcium group

Effect of the drug on maternal weight gain

Weight gain was significant in both the groups (Table 4). Though when compared between the groups, statistical difference was insignificant but values were on the higher side in the trial group. This observation indicates that, the amount of overall nutrition achieved through *Madhuraushadhasiddha Avaleha* was more effective than that of the control group. The *Jivana*, *Balya*, *Brumhana*, *Rasayana* properties of *Madhura Rasa*^[10] could have contributed to this result.

Table 4: Effect of the drug on maternal weight gain

Parameters		Within the group (paired 't' test)					Between the group (unpaired 't' test)			
		Mean BT	Mean AT	D	t	P	d	T	P	df
Weight gain	MS	56.43	60.433	4.000	18.330	<0.001	2.433	0.630	0.534	28
	IC	54.96	58.000	3.033	11.262	<0.001				

MS- Madhuraushada Siddha Avaleha Group IC-Iron and calcium group

Effect of the drug on hematological parameters

Iron Profile: Heamoglobin, serum iron and ferritin showed statistically decrease in the trial group (Table 5). Serum iron was decreased substantially in both the groups. A physiological reduction in the iron levels occurs during pregnancy as the fetal demands are very high especially during the second trimester.^[11] Along with iron rich diet, conventional iron supplementation can only fulfil the iron needs during pregnancy. In this study, even the control group showed reduction in serum iron confirming the extent of iron demand during pregnancy. The increase in serum ferritin may suggest that the drug is capable of supplementing the iron, though not fulfilling the required amount. However, this study does not merely aim to provide iron supplementation alone during pregnancy rather it is a *Rasayana* fulfilling a holistic nutritional supplementation.

Serum Calcium: Calcium is vital for development of fetal skeletal tissue, blood coagulation system

and other metabolic activities.^[12] The trial drug was able to fulfill the calcium needs of pregnancy very efficiently than the contemporary medicine in which deterioration of calcium levels were seen. *Madhraushadhasiddha Avaleha* containing calcium rich drugs such as *Kharjura, Mudgaparni, Mashaparni, Draksha, Shatavari, Vamshalochana* and the milk given as *Anupana* might have contributed for this increase.

WBC: Physiological leukocytosis (increase in white blood cells) without the association of any known disease process is common in pregnancy.^[13] The number of leukocytes in peripheral blood increases considerably during pregnancy. The total mass of WBC also increases to fill the increased blood volume. Increase in WBC count was seen in both the study groups while trial group showed the higher range, suggesting the increase in the immune response.

Table 5: Effect of the drug on hematological parameters

Parameters		Within the group (paired 't' test)					Between the group (unpaired 't' test)			
		Mean BT	Mean AT	D	t	P	d	T	P	df
Serum Ferritin	MS	8.977	12.667	3.690	2.870	0.012	16.821	3.005	0.006	28
	IC	25.003	29.488	4.485	0.659	0.520				
Serum Calcium	MS	9.273	9.653	0.380	1.351	0.198	0.693	3.039	0.005	28
	IC	9.093	8.960	0.133	0.561	0.584				
WBC	MS	10006.66	10773.33	766.66	460.60	0.118	186.66	0.241	0.811	28
	IC	9993.33	10586.66	593.33	1.044	0.314				
Hb	MS	10.217	9.417	0.800	4.413	<0.001	1.900	4.138	<0.001	28
	IC	10.117	11.317	1.200	3.838	0.002				
Serum Iron	MS	80.417	66.071	14.34	2.394	0.031	3.833	0.432	0.669	28
	IC	77.976	69.904	8.072	0.868	0.400				

MS- Madhuraushada Siddha Avaleha Group

Hb- Hemoglobin, IC-Iron and calcium group

Effect of the drug on maternal immunological parameters

The immunoglobulin IgG remained constant throughout the study period in the trial group while in the control group it was decreased. IgM levels increased in the trial group in comparison with a considerable reduction in IgM values in the control group, thus, proving the definite role of immuno-

modulatory effect of the trial drug (Table 5). This suggests that the trial drug possessed immunomodulatory activity improving the maternal immunity. Enhancement of maternal immunity directly influences the fetus as the immunoglobulins are passively transferred to fetus by mother during pregnancy. Humoral immunity also increases passive immunity.^[14]

Table 6: Effect on maternal immunological parameters

Parameters		Within the group (paired 't' test)					Between the group (unpaired 't' test)			
		Mean BT	Mean AT	D	t	P	d	T	P	df
IgG	MS	1270.647	1272.047	1.400	0.029	0.977	250.70	2.284	0.030	28
	IC	1561.213	1529.413	31.80	0.369	0.718				
IgM	MS	205.680	218.533	12.85	1.074	0.301	66.807	2.722	0.011	28
	IC	165.287	151.727	13.56	1.440	0.172				

MS- Madhuraushada Siddha Avaleha Group

IgG- Immunoglobulin G

IC-Iron and calcium group

IgM- Immunoglobulin M

Probable Mode of Action

The efficacy of the drug is the net effect of its ingredients and the synergistic action of the combination. In the *Madhuraushadha Sidda Avaleha*, *Balya* and *Brumhana* effect of the drugs *Mudgaparni*, *Mashaparni*, *Bala*, *Gokshura*, *Kharjura*, *Draksha*, *Ashwagandha*, *Shatavari*, *Vamshalochana*, *Jivanti* and *Kshira*^[15] could be the strong basis for significant increase in maternal weight gain.

The drugs *Gokshura*, *Kharjura*, *Ashwagandha*, *Shatavari* and *Vamshalochana* possess the properties *Dipana* and *Pachana*^[16]; *Mudgaparni*, *Bala*, *Gokshura*, *Kharjura*, *Vamshalochana*, possess *Krimi Hara*^[17] action. Collectively these drugs increase the appetite, does *Amapachana*, relieves *Aruchi*, *Ananna bhilasha* and *Hrullasa* there by increases the digestion and assimilation thus resulting in proper utilization of the nutrients and successfully overcomes GIT disturbances due to physiological alterations. By working at the level of *Dhatvagni* they revitalize metabolic activity resulting in improved nutritional status at the *Dhatu* level.

Shotahara and *Mootrala* properties of *Mudgaparni*, *Mashaparni*, *Gokshura*, *Ashwagandha*, *Shatavari*, *Vamshalochana*^[18] and *Bala*, *Gokshura*, *Kharjura*, *Draksha*, *Jivanti*^[19] respectively in the trial drug, have successfully limited the incidence of pedal edema even in the most anticipated 7th month of pregnancy.

The *Prajasthapana* effect^[20] of *Mudgaparni*, *Mashaparni*, *Bala*, *Gokshura*, *Draksha*, *Ashwagandha*, *Shatavari*, *Jeevanti* and *Ghritha* might have helped in *Garbha Sthirakarana*, prevented the preterm labour and may also counteract those factors causing *Garbha Upaghata* and *Garbha Hani* hence facilitating *Kaala Prasava*.

The common pregnancy discomforts such as pain abdomen, backache and pain in legs caused by the *Vata* vitiation have been counteracted by *Vata Anulomana* and *Vata Hara*^[21] properties of *Mashaparni*, *Gokshura*, *Kharjura* etc.

Bala, *Gokshura*, *Kharjura*, *Draksha*, *Shatavari*, *Jivanti* being *Hrudya*^[22] are wholesome to *Garbhini*. It is conducive for the *Manas* which contribute towards the *Saumanasya* of the *Garbhini*.

Mashaparni *Bala* *Shatavari* *Jivanti* *Vamshalochana* *Pippali* *Twak* being *Rakta Vikara Hara* may act as *Rakta Shodhaka*^[23] and improve the *Varna* of *Garbha* and *Garbhini* counteracting the *Varna Hani* of 6th month.

Bala, *Go Ghrita*, *Jivaniya* and *Rasayana* group of drugs being *Ojovardhaka*, *Tejovardhaka* and *Veerya Vardhaka*^[24] induce *Bala*, *Vyadhikshamatva* or immunity by their *Prabhava*.

Medhya properties^[25, 26] present in the trial drug may also alleviate the symptoms of anxiety, depression and other psychiatric manifestations of the mother during pregnancy and even during postpartum period.

Drugs like *Mudgaparni*, *Mashaparni*, *Bala*, *Gokshura*, *Ashwagandha*, *Shatavari*, *Ghritha* and *Ksheera* have *Rasayana*^[27] properties. *Rasayana* does *Prinana* of *Sarvadhatus*, thereby rejuvenates the maternal *Dhatu*s. The immuno-modulatory action of the drugs boosts the maternal immune system protecting the *Garbhini* and the *Garbha* within. It also possesses adaptogenic effect^[28] i.e, when administered, stabilizes the physiological processes and promote homeostasis. It increases resistance to stressors, which may prove to be very essential during the pregnancy.

CONCLUSION

Madhuraushadha Siddha Avaleha acts as *Rasayana*, fulfilling the nutritional demands and boosting the immunity in the *Garbhini*. The result of the present study not only confirms the nutritional benefits of *Madhuraushadha Siddha Avaleha*, it even improved the immuno-modulatory status of the mother, thus acting as *Rasayana* during the 6th and 7th month of pregnancy. *Garbhini Rasayana* can work as a platform to build up holistic approach in this regard and this would be a great contribution from fraternity of Ayurveda, to the branch of obstetrics and thus to the mankind.

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